REMARKS

The Examiner's Action of January 27, 2004 has been received and its contents carefully considered. Reconsideration is respectfully requested in view of the following comments.

Claims 1-3 and 8-27 are currently pending in the instant application.

Rejections under 35 USC 103(a)

Claims 1-3, 9-11, 16-18, 20-22 and 27 have been rejected under Section 103(a) as being unpatentable over Araya et al. (JP 10-219375). Claims 8 and 19 have been rejected under Section 103(a) as being unpatentable over Araya et al. in view of Farzin-Nia et al. Claims 12 and 23 have been rejected under Section 103(a) as being unpatentable over Araya et al. in view of Beyar et al. Claims 13 and 24 have been rejected under Section 103(a) a being unpatentable over Araya et al. in view of Regan. Claims 14 and 25 have been rejected under Section 103(a) as being unpatentable over Araya et al. in view of Kizelshteyn et al. Claims 15 and 26 have been rejected under Section 103(a) a being unpatentable over Araya et al. in view of Besselink et al.

Reconsideration is respectfully requested in view of the following comments.

All of the pending claims have been rejected under Section 103(a) as being unpatentable over Araya et al. as the sole reference or as the primary reference combined with another reference.

As an initial matter, independent claims 1 and 17 as amended require that the alloy comprises both Sn and "one of" Nb and Ta, as opposed to Sn and "at least one of" Nb and Ta recited prior to the instant amendments.

The Examiner points to the Abstract of Araya et al. and notes that this Abstract teaches the presence of a total of Nb and Ta of 20-60%. Based on the Abstract, the Examiner concludes that, according to Araya et al., "one or both Nb and Ta" would be within the scope disclosed by Araya et al.

It is submitted, however, that the Examiner's understanding of Araya et al., is not substantiated by the disclosure in that reference. First, the Abstract in Araya et al. mentions that "[t]he titanium alloy has a composition consisting of, by weight, 20-60%, in total, of Nb and Ta and the balance Ti with inevitable impurities." *Emphasis provided.* It is notable that the Abstract goes on to note that "[i]t is desirable to regulate Nb content and Ta content to >15-50%

and >6-20%, respectively," further reinforcing the fact that Araya et al. expects both Nb and Ta to be present in their composition. Clearly, "Nb and Ta" means exactly that both Nb and Ta must be present. In fact, when Araya et al. mean to refer to components of the composition as being optionally provided, they explicitly mention the same. The Abstract goes on to note that "[o]ne or 2 kinds among 10%Mo; 5% Zr; and 5% Sn are further added to the above titanium alloy." Thus, if Araya et al. had meant for either Nb, or Ta, or both to be present, Araya et al. would have explicitly mentioned so, similarly to the case for Mo, Zr and Sn.

The Examiner had supplied in addition to the Abstract, a computer translation of the reference, with a disclaimer as to its accuracy. Enclosed herewith is a certified translation of paragraph [5] of the reference, which is a more accurate translation. Beyond what is gained from the abstract, more importantly, the Detailed Description in Araya et al. makes clear the need for **both** Nb and Ta stating that the problems were solved by "focusing on the addition of Nb (niobium) *together with* Ta (tantalum) in a respective pre-determined quantity into titanium." (emphasis supplied). Furthermore the disclosure mentions disadvantages present with Nb less than 15%wt and with Ta less than 6%wt. Specifically, at paragraph 5, Araya et al. mention that "in the case of a niobium content not exceeding 15wt%, the α phase separates out in the metal structure," and at paragraph 6 that " [i]f Ta becomes less than 6%wt, elongation begins to run short." The above disclosure again clearly dictates that **both** Nb and Ta need to be present in Araya et al.'s composition.

Araya et al. require that Sn and both Nb and Ta be present in the alloy, and thus teach away from eliminating any of Nb and Ta from the alloy containing Sn. In addition, the data present in Araya et al. all show the presence of Sn along with both Nb and Ta. The teaching of either Nb or Ta being present in the alloy is not only missing from Araya et al., it is taught away from in the reference.

Moreover, independent claims 1 and 17 are both directed to an alloy comprising Sn in an amount of 3-6%. Regarding Araya et al, the Office Action states that "[t]hough Araya et al. fail to meet the claimed range of tin, the range taught by Araya et al is close enough to the presently claimed range that one of ordinary skill in the art would have expected the two alloys to have the same properties." First, as set forth in the response filed on June 20, 2003, Araya et al. expressly teach away from an Sn range in an amount of 3-6%. Araya et al. expressly state that the Sn should be present at no more than 5wt%, which is less than the range specified in claim 1. Araya

et al. add that observance of the stated ranges of the components of their alloy enhances the stability of the same. Thus, a person of ordinary skill would in fact be led away from increasing the amount of Sn present in Araya et al. alloy. The Examiner is using impermissible hindsight. Clearly, the only motivation for the modification of the stated range for Sn comes from Applicants' own invention.

In view of the above, it is submitted that independent claims 1 and 17 are patentable over Araya et al. In addition, it is submitted that independent claims 2, 3, 9-11, 16-18, 20-22 and 27 are patentable over Araya et al. by virtue of being dependent from independent claims 1 or 17, and further for the particular additional features that they recite.

In addition, none of the secondary references overcome the deficiencies of Araya et al. noted above. Thus, it is submitted that all of the pending claims are patentable over the cited combination of references.

CONCLUSION

In view of the above, it is submitted that the application is in condition for allowance. Reconsideration, withdrawal of all grounds of rejection and issuance of a Notice of Allowance are solicited.

The Office is hereby authorized to charge any additional fees or credit any overpayments under 37 C.F.R. §1.16 or § 1.17 to Deposit Account No. 11-0600. The Examiner is invited to contact the undersigned at (202) 220-4201 to discuss any matter regarding this application.

Respectfully submitted,

Date: April 16, 2004

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PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of
Shuji HANADA *et al.*
Appln. No.: 09/710,430 Group Art Unit: 1742
Filed: November 9, 2000 Examiner: Harry D Wilkins, III
For: NOVEL TERNARY ALLOY AND APPARATUS THEREOF

STATEMENT

Commissioner for Patents
Alexandria, VA 22313-1450

Sir/Madam:

I, Hidetaka Ota, residing at Ark Mori Bldg., 13F, 12-32 Akasaka 1-chome, Minato-ku, Tokyo, Japan hereby state that:

I well understand the Japanese and English languages and attached is an accurate English translation made by me of paragraph [0005] of Japanese Patent Publication No. Hei.-10-219375, published on August 18, 1998.

Date : April 7, 2004 Name :

Hidetaka OTA

Araya (JP 10-219375)

[0005]

[Means for Solving the Problems]

The present invention has been achieved, as a result of an extensive and concentrated research on β-titanium alloys conducted by the inventors for the purpose of solving the above-cited problems, by focusing on the addition of Nb (niobium) together with Ta (tantalum) in a respective pre-determined quantity into titanium.

Namely, the titanium alloy of the present invention contains Nb and Ta in a total content of 20 to 60wt %, whereby the remainder consists of titanium and inevitable impurities. By formulating the alloy in such compositions, the aforementioned problems can be solved. By way of precaution, the upper limit for the sum of the niobium and tantalum is preferably set at 50wt %. In the present titanium alloy, the content of niobium is preferably in the range of from 15 to 50wt %. The reason lies in the fact that, in the case of a niobium content not exceeding 15wt %, the α-phase separates out in the metal structure while, on the other hand, for a niobium content exceeding 50wt %, elongation begins to go short. Thus, a more preferable upper limit for the niobium content is 45wt %.

【特許請求の範囲】

【請求項1】Nb及びTaを合計で20wt%～60wt%含み、残部がTiと不可避的不純物からなることを特徴とするチタン合金。

【請求項2】前記Nbの含有量が15wt%超～50wt%以下であることを特徴とする請求項1に記載のチタン合金。

【請求項3】前記Taの含有量が6wt%超～20wt%以下であることを特徴とする請求項1又は2に記載のチタン合金。

【請求項4】前記チタン合金に、更に10wt%以下のMo、5wt%以下のZr、又は、5wt%以下のSnの一種又は二種以上を添加したことを特徴とする請求項1乃至3に記載のチタン合金。

【請求項5】前記チタン合金に溶体化処理を施し、このチタン合金の結晶粒を再結晶させたことを特徴とする請求項1乃至4に記載の硬質組織代替材。

【請求項6】前記溶体化処理の後に、前記チタン合金に時効処理を施したことを特徴とする請求項5に記載の硬質組織代替材。

【発明の詳細な説明】

【0001】

【発明の属する技術分野】本発明は、新規なチタン(Ti)合金に関し、特に生体の人工骨材又はその一部、或いはそれらの補助材のような硬質組織代替材に適したチタン合金と、このチタン合金を用いた硬質組織代替材に関する。

【0002】

【従来の技術】一般に、歯科用の人工歯根や医療用の人工骨材には、Ti-6wt%Al-4wt%Vに代表されるチタン合金が適用又は検討されている。これは、チタンが他の金属に比べ、生体内において高い適応性を有することによる。しかし、種々の研究によると、上記チタン合金のうちV(バナジウム)は、生体の細胞に対し、毒性を有することが指摘されている。このため上記Vに替えてNbやFeを添加したTi-6wt%Al-7wt%Nbや、Ti-5wt%Al-2.5wt%Fe等の所謂α+β型のチタン合金が提案されている。しかしながら、これらの合金中のAl(アルミニウム)は、ある種の痴呆症を招くという指摘もなされている。

【0003】そこで、上記毒性やアレルギー性の指摘がない金属元素を用い、α+β型チタン合金よりも高い伸びと、優れた冷間加工性を有すると共に、弾性率を低くして生体内の硬質組織に近付けるべくβ型チタン合金が提案されるようになった。このβ型チタン合金には、例えばTi-13wt%Nb-13wt%Zr、Ti-16wt%Nb-10wt%Hf、Ti-15wt%Mo、Ti-15wt%Mo-5wt%Zr-3wt%Al、Ti-12wt%Mo-6wt%Zr-2wt%Fe、Ti-15wt%Mo-2.8wt%Nb-0.2wt%Si-0.26wt%O等が含まれている。しかしながら、上記各β型チタン合金のうち、どのような成分組成の合金が人工骨材等のような硬質組織代替材に適しているか、あまり研究されておらず、未だ不明確であった。

【0004】

【発明が解決すべき課題】本発明は、上記従来の技術に鑑み、生体の硬質組織代替材に特に適し、生体に対し毒性やアレルギーが少なく、適度な強度と高い伸び率、及び低い弾性率を有すると共に、耐食性にも優れた生体の活動にフィットする新たなチタン合金と、このチタン合金を用いた硬質組織代替材を提供することを目的とする。

【0005】

【課題を解決するための手段】本発明は、上記課題を解決するため、β型チタン合金について発明者らが鋭意研究した結果、チタンに対しNb(ニオブ)と共にTa(タンタル)を併せて所定量ずつ添加することに着目することにより得られたものである。即ち、本発明のチタン合金は、Nb及びTaを合計で20wt%～60wt%含み、残部がTiと不可避的不純物からなることを特徴とする。係る組成の合金にすると、上記課題を解決することが可能となる。尚、上記NbとTaを合計する範囲の上限は、50wt%とするのが望ましい。このチタン合金のうち、Nbの含有量は、15wt%超～50wt%以下の範囲内にあることが望ましい。Nbが15wt%以下では、金属組織中にα相が析出し、一方、Nbが50wt%を超過すると、伸びが不足し始めるためであり、Nbのより望ましい上限は45wt%である。

【0006】また、前記Taの含有量は、6wt%超～20wt%以下の範囲内にあることが望ましい。Taが6wt%以下になると伸びが不足し始め、一方、Taが20wt%を超過すると、合金自体の融点が上がり過ぎるためであり、Taのより望ましい上限は15wt%である。更に、上記の各チタン合金に対し、更に、10wt%以下のMo(モリブデン)、5wt%以下のZr(ジルコニウム)、又は、5wt%以下のSn(錫)の一種又は二種以上を添加したものも含まれる。係る各元素を添加することにより、一層安定した特性を有するチタン合金を得ることが可能となる。

【0007】また、本発明には、上記チタン合金を用い、これらに溶体化処理を施して、その結晶粒を再結晶させたことを特徴とする硬質組織代替材、及びその溶体化処理の後に更に時効処理を施した硬質組織代替材も含まれる。上記溶体化処理及び/又は時効処理を施すことにより、β相における結晶粒が微細化され、強度を適正に高め、且つ伸びと弾性率を適正化することができる。係る硬質組織代替材によれば、骨、又は歯根として、或いは、義歯、義肢、又は義足等の構成部材として用いることで、生体の活動に馴染んだ特性及び効果を得ることができ、医療技術の向上に寄与することが可能となる。